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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,381	08/15/2006	Annaliesa S. Anderson	21490YP	5673
210	7590	08/14/2007	EXAMINER	
MERCK AND CO., INC			DEVI, SARVAMANGALA J N	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	
			1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,381	ANDERSON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08/15/06.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Lack of Unity

- 1) Claims 1-15 are under prosecution.
- 2) The instant application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-7, drawn to a polypeptide immunogen comprising an amino acid sequence at least 85% identical to SEQ ID NO: 1, which provides protective immunity against *S. aureus* and does not contain amino acids 261-294 of SEQ ID NO: 7 and a composition comprising the same.
- II. Claims 8-10, drawn to a nucleic acid comprising a nucleotide sequence encoding the polypeptide of invention I.
- III. Claim 11, drawn to a method of making a *S. aureus* polypeptide that provides protective immunity using a recombinant cell comprising the nucleic acid.
- IV. Claims 12-15, drawn to a method of inducing a protective immune response in a patient by administering an amount of the polypeptide of invention I.

- 3) Inventions I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of invention I is a polypeptide immunogen comprising an amino acid sequence at least 85% identical to SEQ ID NO: 1, which provides protective immunity against *S. aureus* and does not contain amino acids 261-294 of SEQ ID NO: 7 and a composition comprising the same. However, such a polypeptide immunogen was already disclosed in the art at the time of the invention. For instance, Brummel *et al.* (WO 03/011899 A2, cited on international report) disclosed a vaccine composition comprising a carrier and/or adjuvant and a polypeptide immunogen of MW 38,745 comprising an amino acid sequence at least 99% identical to SEQ ID NO: 1 (ADA89548) which does not contain amino acids 261-294 of SEQ ID NO: 7 and which elicits opsonic (protective) antibodies. The polypeptide further comprises a secretion signal to facilitate purification. See Table 8 on page 140; claims 4-12; and pages 10-16. Thus, the product of claim 1 does not define over the prior art. Although the product of invention I,

and the method of using the product of invention IV or the method of making the product of invention III, is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, the special technical feature is not a unifying feature. Technically, the absence of special technical feature permits the separation of the method of using or making the product from the product itself. The special technical features of the subsequently claimed inventions are delineated above. The second claimed nucleic acid product of invention II does not share significant structural elements with the polypeptide product of invention I. A polypeptide is a single chain molecule which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. The methods of inventions III and IV do not share significant steps and method objectives.

4) The Office has separated product and process claims based on lack of unity. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5) In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See ‘Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)’, 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35

Application/Control No. 10/589,381
Art Unit: 1645
August 2007

U.S.C. 121 does not apply where the lack of unity is withdrawn by the examiner before the patent issues.
See MPEP § 804.01.

6) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300.

7) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

August, 2007


S. DEVI, PH.D.
PRIMARY EXAMINER